DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC

FEB 8 2002

Mr. Michael F. Jacobson, Executive Director
Center for Science in the Public Interest
1875 Connecticut Ave., NW
Washington, DC 20009

Re: Docket Number 01P-0320/CP1

Dear Mr. Jacobson:

This letter is in response to your citizen petition dated July 26, 2001, which was filed on July 26, 2001, under Docket Number 01P-0320/CP1. You requested that the Food and Drug Administration (FDA) amend its labeling regulations to establish format standards for ingredient lists on the labels of food products to improve the "readability" of ingredient lists.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other agency priorities and limited availability of resources. FDA's Center for Food Safety and Applied Nutrition (CFSAN) is focused on food safety and, after the September 11 terrorist attacks, on counter-terrorism. As you may be aware, CFSAN recently released its 2002 program priorities. Your petition was not placed on CFSAN's 2002 Program Priorities. However, as you noted in your letter, label legibility and readability would assist consumers who suffer with food allergies and intolerances in addition to helping other individuals. As stated in item 1.11.7, of our program priorities, we plan to develop a strategy to improve the labeling of the most common allergens. We will consider the points raised in your petition when we address better labeling of allergens.

Sincerely yours,

Christine Lewis Taylor

Christine Lewis Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

LET1

01P-0320

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Petition for Proposed Rulemaking	)	Docket No. ______
to Establish Format Requirements	)	
for Ingredient Lists	)	
______________________________	)	

Submitted by the

Center for Science in the Public Interest

July 26, 2001

Michael F. Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest
1875 Connecticut Ave. NW
Washington, D.C. 20009
(202) 332-9110

01P-0320

CP1

July 26, 2001

Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

CITIZEN'S PETITION

The Center for Science in the Public Interest (CSPI)[1] submits this petition, pursuant to §4(d) of the Administrative Procedure Act, 5 U.S.C. §553(e), and §§201(n), 403(f), 403(i) and 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§321(n), 343(f), 343(i) and 371(a), and 21 C.F.R. §§10.30, requesting that the Commissioner of the Food and Drug Administration adopt a regulation that establishes format standards for ingredient lists on the labels of food products.

I. *Action Requested*

We request that the Food and Drug Administration (FDA) adopt a new regulation that would improve the "readability"[2] of ingredient lists on food labels by establishing explicit format

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[1] CSPI is a non-profit consumer organization supported by approximately 800,000 members. CSPI has worked since 1971 to improve national health policies. We have been especially concerned about the use of food labeling to promote health.

[2] Generally, "readability" does not refer to reading comprehension, but to whether an extended amount of text is easy to read. "Legibility" refers to whether a short burst of text (such as a headline or sign) is instantly recognizable. Robin Williams, *The Non-Designer's Type Book: Insights and techniques for creating professional-level type* 33 (1998). In this petition, we will use the term "readability."

standards. Specifically, CSPI requests that the new regulation[3] specifies a minimum type size;[4] establishes allowable type styles; and requires the use of upper- and lower-case letters,[5] left justification only, sufficient color contrast,[6] and standard kerning (space between letters) and leading (space between lines). In developing that regulation, FDA should consider the standards for formatting elements established for the "Nutrition Facts," label, the "Supplement Facts" label, and the new label for over-the-counter (OTC) drugs.[7]

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[3] Instead of adopting a new regulation, FDA could revise its existing regulation, 21 C.F.R. §101.15(a)(6), which provides general guidance on the "prominence and conspicuousness" of required label information, including ingredient lists. As discussed *infra*, there are additional regulations establishing specific format standards for nutrition information for conventional foods and dietary supplements, as well as for information regarding over-the-counter (OTC) drugs.

[4] Typically, the smallest recommended font size for written materials for the general public is 10-point, while larger font sizes are recommended for populations where low-literacy, age, or impaired vision are significant factors. 65 Fed. Reg. 81082, 81096 (2000)(*citing* Kripalani, S., "The Write Stuff: Simple Guidelines Can Help You Write and Design Effective Patient Education Materials," *Texas Medicine*, vol. 91, pp. 40-45, 1995; Backlinger, C.L., and P.A. Kingsley, *Write it Right: Recommendations for Developing User Instructions for Medical Devices Used in Home Health Care*, Department of Health and Human Services, Publication No. FDA 93-4258, 1993; Mettger, W., and J. Mara, *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers*, Bethesda, MD, National Cancer Institute, Publication No. NIH 95-3594, 1994). While we understand that FDA must balance the benefits of larger-size type with the limitations imposed by small food packages, we urge the agency to establish a minimum type size for ingredient lists that is the largest practicable, with smaller type sizes allowed only when necessary.

[5] *See* Tufte, E., *Envisioning Information* 51 (1990)(*citing* Albers, J., *Interaction of Color* 4 (1975)("Words consisting of only capital letters present the most difficult reading -- because of their equal height, equal volume, and, with most, their equal width.")

[6] We believe that the FDA should require that ingredient lists, like the "Supplement Facts" label, be printed in all black or one color type, on a white or other neutral contrasting background, whenever practical. *See* 21 C.F.R. 101.36(e)(3)(iii).

[7] *See infra* notes 35-41 and accompanying text for a discussion of the format standards for these labels.

Another way to make the ingredient list easier to read would be to divide the list into major ingredients and minor ones (those present in amounts of 2% or less by weight),[8] and to use bullets to separate individual ingredients.[9] Further, FDA should consider requiring that the ingredient list be placed directly under the "Nutrition Facts" label.[10] In developing an ingredient-list format regulation, the agency should conduct consumer testing to ensure that the format standards selected will result in highly readable ingredient lists.

Over the past decade, FDA has recognized the importance of clear, easy-to-read product labels for foods, dietary supplements, and over-the-counter drugs and has revised its regulations to better ensure readable labels. This petition asks the agency to extend those efforts by adopting a regulation that specifies standards that would require more-readable ingredient lists on food products. A relatively small change in the agency's rules could greatly increase consumers' use of a valuable information tool to protect and promote public health.[11]

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[8] This would not be required when the product has less than four ingredients, or when it has no ingredients that constitute 2% or less, by weight, of the total product.

[9] One way to distinguish individual ingredients from their component ingredients (which appear in parentheses) would be to print the component ingredients in a slightly lighter type.

[10] We have included as Exhibit 1 a side-by-side comparison of an example of an actual ingredient list and a redesign of the same list, done by Greenfield-Belser, Ltd., the same firm that created the "Nutrition Facts" label. It follows a number of the design elements of the "Nutrition Facts" label and incorporates many of the features mentioned above (Exhibit 1 also includes an annotated version of our proposed redesigned ingredient list which includes all of the design specifications) . It also includes a warning regarding the possible presence of certain food allergens. As noted *infra*, note 26 and accompanying text, CSPI supports the petition filed by the Attorneys General of nine states to provide clearer label information about food allergens.

[11] CSPI has petitioned the Bureau of Alcohol, Tobacco, and Firearms (ATF), asking it to amend the regulations concerning the placement, legibility, and noticeability of the congressionally mandated health warning statement required to appear on the labels of all alcohol beverages. We asked that the regulation require the warning to be placed prominently on

II. *Statement of Factual Grounds*

A. Current Ingredient Lists are Difficult to Read

For more than half a century, the ingredient list has been the most direct way for consumers to determine the contents of multi-ingredient foods. While the Nutrition Facts label provides important health information that enables consumers to determine the nutritional content of food products, it does not plainly inform consumers about which products contain the greatest amounts of healthful ingredients. For example, while a "Nutrition Facts" label discloses the fiber content of a serving of a food, it does not inform the consumer as to the amount of whole grains in the product. Nutrition labels also fail to disclose the amounts of added sugars in a food product. This is important information that consumers need to know to make healthful food choices. Therefore, it is essential that the ingredient list be printed in a manner that maximizes readability.

While federal law[12] and regulations[13] require that ingredients be listed on the packages of multi-ingredient food products in descending order of prominence by weight, they do not guarantee that consumers can actually read the ingredient information. That fact becomes readily apparent after a visit to the supermarket, where store shelves are stocked with foods bearing unreadable, or barely readable, ingredient lists that sabotage consumers' efforts to determine a

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the front label, that it be printed horizontally, in red or black type on a white background, surrounded by a lined border, and that the text of the warning be printed in upper- and lower-case lettering. ATF has put our petition out for comment. *See* 66 Fed. Reg. 28135 (2001).

[12] 21 U.S.C. §343(i).

[13] 21 C.F.R. §101.4.

product's ingredients. Most ingredient lists are printed in all capital letters. Many are fully justified, have too little space between lines, or use condensed type.[14] Long lists of ingredients, with the ingredients of ingredients listed in parentheses, are particularly hard to follow.[15]

Other ingredient lists are difficult to read because they are printed on metallic paper that reflects light;[16] use a color of ink that contrasts poorly with the color of the label;[17] or the list is printed on clear, cellophane wrapping, and the color of the product obscures the ingredient information.[18] On some labels, the ingredient list is difficult to distinguish from other label information,[19] while, on others, it is completely covered.[20]

While ingredient lists can be difficult to read for even the average consumer with excellent eyesight, current labels pose a particularly tough challenge for older persons.[21]

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[14] *See* Exhibit 2.

[15] *See* Exhibit 3.

[16] *See* Exhibit 4.

[17] *See* Exhibit 5.

[18] *See* Exhibit 6.

[19] *See* Exhibit 7.

[20] *See* Exhibit 8.

[21] Virtually every person, by age 65, will suffer some loss in ability to focus, to resolve images, to discern colors and to adapt to light. American Association of Retired Persons, *Truth About Aging: Guidelines for Accurate Communications* 25 (1986). Over 60% of those considered visually impaired are older persons. In fact, many people's eyesight begins deteriorating at about age 30. Even with corrective lenses or medical treatments, millions of Americans have less than 20/20 vision.

B. More Readable Ingredient Lists Would Promote the Public Health

Clear ingredient lists would promote the public's health by enabling consumers to choose or avoid certain ingredients. Survey data consistently demonstrates that consumers use ingredient lists to avoid certain ingredients.[22] Thus, a clear, easily readable ingredient list would assist those consumers who want to avoid unhealthy ingredients, such as hydrogenated fats, or to eat more whole grains. Such consumers need to be able to read the ingredient information on a product label in order to make the right food choices.

Moreover, for consumers suffering from food allergies, readable ingredient lists can be a matter of life and death. Food allergies are becoming increasingly prevalent in the United States. Up to 8 percent of children less than three years of age and approximately 2 percent of the adult population suffer from food allergies.[23] Food allergens cause an estimated 2,500 anaphylactic reactions in the U.S. each year,[24] while an estimated 150 Americans die each year from severe allergic reactions to food.[25] A more readable ingredient list should help reduce the number of reactions and deaths caused by food allergies.

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[22] A 1995 survey found that 44% of respondents used the ingredient list to avoid certain ingredients. *1994 Food Label Use and Nutrition Education Survey, 1995 Health and Diet Survey.* FDA's own data for the period 1978-1986 show that overall use of the ingredient list remained constant at 75-80% of the population. In 1986, 68% of the population used the list to avoid or limit ingredients. J. Heimbach and A. Levy, *Journalists' Conference* (October 1987).

[23] Hugh A. Sampson, *Food Allergy, Part 1: Immunopathogenesis and Clinical Disorders,* 103 J. Allergy Clin. Immunol. 717 (1999).

[24] A. Wesley Burks & Hugh A. Sampson, *Anaphylaxis and Food Allergy*, 17 Clin. Rev. in Allergy and Immunol. 339 (1999).

[25] Raymond Formanek Jr., *Food Allergies: When Food Becomes the Enemy at* http://www.fda.gov/fdac/features/2001/401_food.html.

We recognize that the FDA is currently considering a petition from state attorneys general to develop regulations that would provide clearer information on labels about strong allergens[26] and has scheduled a public meeting on that issue. Such activity is necessitated in part by FDA's inadequate enforcement of the requirement of section 403(f) that mandated label information be "prominent and conspicuous" as applied to ingredient lists.

However, the attorneys' general petition and most other discussions of food allergies focus only on the eight most common and severe allergens. Many other foods cause allergic reactions, some of which can be severe, in certain individuals. Such foods include strawberries, apples, carrots, parsnips, celery, hazelnuts, potatoes, and kiwi.[27] More-readable ingredient lists would benefit consumers who suffer allergic reactions to those ingredients as well.

More-readable ingredient lists on food labels would also help those consumers who have food intolerances. Food intolerances are a much more common problem than food allergies. For example, an estimated 80 percent of African-Americans suffer from lactose intolerance (difficulty digesting milk), as do many people of Mediterranean or Hispanic origin.[28] Being able

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[26] In their petition, the Attorneys General from nine states request that FDA amend its regulations to better protect those suffering from food allergies. They ask the agency to include a warning in the ingredient list of the presence of a food allergen, require the inclusion on the label of a toll-free number to call for information on food allergens, and clearer identification in the ingredient list of flavorings and additives derived from known food allergens. The petition also requests that the agency revise its good manufacturing practice rules for food companies to prevent the migration of allergenic substances from equipment and packaging. CSPI strongly endorses that petition.

[27] http://www.allergylearninglab.com/about/food/index.html?id=4195215 (June 21, 2001).

[28] *Food Allergies: Rare but Risky*, FDA Consumer (May 1994).

to readily identify any suspect ingredient could save many consumers from significant discomfort.

Still other consumers have what are sometimes termed "food sensitivities." For example, some people have a sensitivity to sulfites, which are preservatives used primarily to prevent or reduce discoloration of light-colored fruits and vegetables, such as dried apricots or dehydrated potatoes. Consumption of sulfites by sensitive individuals can prompt a severe anaphylactic reaction, which may be life-threatening. According to the American Academy of Asthma, Allergy, and Immunology, the most common food additives that may cause reactions include aspartame, benzoates, BHA and BHT, FD&C dyes Yellow No. 5 and Red No. 3, monosodium glutamate (MSG), nitrates/nitrites, parabens and sulfites."[29]

In addition, a more readable ingredient list would help consumers taking certain prescription or over-the-counter medications avoid food ingredients that may interact with their medications. For example, people who use bronchodilators to treat asthma, bronchitis, or emphysema need to be careful about what foods they consume: They should avoid caffeine because it will enhance the stimulating effect of their medication. People taking certain diuretics should avoid potassium-rich foods like bananas, oranges, and green leafy vegetables, as well as salt substitutes that contain potassium.[30]

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[29] http://www.aaaai.org/public/publicedmat/tips/foodallergy.stm (June 21, 2001). There are varying amounts of evidence regarding each of those additives.

[30] *See* U.S. Food and Drug Administration and the National Consumers League, *Food & Drug Interactions* (1998). Many other diuretics, however, deplete potassium reserves and require increased consumption of potassium-rich foods.

A more-readable ingredient list would also better enable consumers to avoid any ingredients or additives that they believe may pose a health risk. Some consumers are aware of

III. *Statement of Legal Grounds*

In adopting a regulation governing the prominence and conspicuousness of ingredient lists, FDA can rely on numerous provisions of the U.S. Federal Food, Drug, and Cosmetic Act (FFDCA). Sections 201(n) and 403(a) of the Act[31] prohibit the misbranding of any food product. Also, section 701(a) of the FFDCA[32] authorizes the agency to adopt regulations for the "efficient enforcement of this Act."

One criterion for finding a food product misbranded, and therefore in violation of the Act under Section 301(b),[33] is if

> any word, statement, or other information required . . . to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.[34]

An existing FDA regulation, 21 C.F.R. §101.15(a)(6), identifies situations in which required information on a food label or labeling would lack the "prominence" and "conspicuousness" that would "render it likely to be read and understood by the ordinary individual." These include "[s]mallness, or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or

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evidence that acesulfame-K, aspartame, BHT, and other additives may pose a health risk, though the FDA has not agreed that the evidence is sufficient to warrant a ban. A more-readable ingredient list would help those consumers avoid substances whose safety has been questioned.

[31] 21 U.S.C. §§ 321(n) and 343(a).

[32] 21 U.S.C. §371(a).

[33] 21 U.S.C. §331(b).

[34] 21 U.S.C. §343(f).

crowding with other written, printed, or graphic matter."

We maintain that section 101.15(a)(6) is ineffective because it fails to set forth specific provisions regarding type, size, and format. Therefore, it has failed to ensure that ingredient lists are "prominent and conspicuous." As noted above, many current ingredient lists are unreadable because of smallness of type, use of all capital letters or ornate type style, insufficient spacing between letters, words, and lines, and insufficient color contrast between ink and label paper. For that reason, we believe that those products are misbranded under the FFDCA. In order to prevent these ongoing violations of the Act, we urge the agency to adopt a regulation establishing more specific requirements regarding the format for ingredient lists.

In four separate rulemakings over the past decade, FDA has adopted regulations that are more specific than 21 C.F.R. §101.15(a)(6) to ensure the readability of label information. It has recognized that product labels can be made more readable by improvements in label design. Three separate regulations, and one proposed rule, dictate format standards for labels to ensure that consumers can read the information required by the agency to appear on product labels.

- In January 1993, FDA adopted, as part of its regulations implementing the Nutrition Labeling and Education Act (NLEA), a rule specifying format elements for mandatory nutrition labeling for food products. The regulation requires that nutrition labels utilize a single easy-to-read type style; upper- and lower-case letters; and at least one-point leading. The regulation also requires that the letters never touch, and that the nutrition information be printed in at least 6-point type.[35]

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[35] 21 C.F.R. §101.9(d)(1)(ii)-(iii).

In the preamble to that regulation, FDA noted that it "expects that unless impractical, the nutrition information will be presented in dark type on a light color background" and that "it will not be acceptable to reduce the contrast between print and background, whether by light letters on a light background or dark letters on a dark background, to the point where readability of the label is significantly downgraded." FDA also reiterated its view that specific requirements for graphic elements were necessary in order to prevent confusion.[36]

In adopting this format regulation, FDA expressly acknowledged that "the readability of the nutrition label needs to be improved to help older and vision-impaired consumers who otherwise would be effectively denied access to nutrition information of food packages."[37]

Furthermore, the NLEA mandated a report, which reviewed various state food labeling requirements to determine whether they were preempted by federal law. This report, prepared by the National Academy of Sciences (NAS), included a recommendation that FDA consider improving label readability by developing specific format requirements (establishing a minimum type size, font, and contrasting colors for background and print) for all information required on food labels under section 403(f). It noted that a more specific federal regulation would eliminate ambiguity regarding the meaning of "prominent" and "conspicuous" and would simplify compliance.[38]

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[36] 58 Fed. Reg. 2079, 2136 (1993).

[37] *Id.*

[38] *See* Institute of Medicine, *Food Labeling: Toward National Uniformity* 103 (1992).

• In 1997, FDA, as part of its implementation of the Dietary Supplement Health and Education Act (DSHEA), issued a regulation requiring that all dietary supplements bear a "Supplement Facts" label similar in design to the "Nutrition Facts" label on conventional food products. In addition to the format criteria established for the nutrition label, the label format for dietary supplements also requires that the label be printed in "[a]ll black or one color type, printed on a white or other neutral contrasting background whenever practical."[39] In the preamble to that rule, FDA noted that those requirements "are designed to maximize the legibility of the label."[40]

• In March 1999, the agency issued its final rule regarding the label format for OTC drugs.[41] That rule requires that the information be "legible and clearly presented," that it not appear in reverse type, that the letters not touch, and that the leading be at least 0.5-point. It also sets the minimum type size at 6 point.

• A pending proposal would establish format criteria for the physician labeling that accompanies prescription medicines.[42] The FDA is proposing a minimum type size of 8 point, the use of bold type in headings, and a prohibition of reverse type.

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[39] 21 C.F.R. §101.36(e)(3)(iii).

[40] 60 Fed. Reg. 67194, 67205 (1997). The agency did allow the use of 4.5 point type on supplement labels in limited circumstances (for small packages) and made clear that small type would be used mostly for numerical information on product content, generally presented in tabular format with ample white space. It rejected a request that 4.5 point type also be the minimum type size allowable for the labels of OTC drug products, noting that OTC labels consist largely of running text. 64 Fed. Reg. 13254, 13265 (1999).

[41] 21 C.F.R. § 201.66(d).

[42] *See* 65 Fed. Reg. 81082 (2000).

In addition, voluntary guidelines, issued in December 1996 by a congressionally-created advisory committee, recommend that information for consumers accompanying prescription medicines be printed in no smaller than 10-point type; in an easy-to-read type style; in upper- and lower-case lettering; with adequate spacing between letters, lines, and paragraphs, and with sufficient contrast between the color of the ink and the background.[43]

Just as FDA relied, in part, on its general authority to prohibit misbranding and to "efficiently enforce" the Act when it established format specifications for nutrition labels, dietary supplement labels,[44] and OTC drug labels,[45] it can rely on those authorities to establish specific format standards for ingredient labels on food products. We urge the agency to take such action.

IV. *Environmental impact*

The action requested is subject to a categorical exclusion under 21 C.F.R. §25.30(k) and does not require the preparation of an environmental assessment.

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[43] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, "Action Plan for the Provision of Useful Prescription Medicine Information," Appendix G, Washington, D.C., 1996. *See* Exhibit 9 for a copy of those guidelines.

[44] In addition to relying on its authority under sections 403(a) and 701(a) of the Act to prohibit misbranding in adopting format standards for the "Nutrition Facts" and "Supplement Facts" labels, FDA also relied on a provision in the NLEA that directed the Secretary of Health and Human Services (and the FDA, by delegation) to issue regulations that require the nutrition information to be conveyed in a manner that enables the public to "readily observe and comprehend" nutrition information. *See* Public Law No. 101-535, Section 2(b)(1)(A).

[45] Section 502(c) of the FFDCA, 21 U.S.C. §352(c), provides that information required on a drug label must be "prominent and conspicuous."

V. *Economic impact*

No statement of economic impact of a revision of the rule governing the format of the ingredient list is required at this time.

VI. *Certification*

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

Michael Jacobson, Ph.D.
Executive Director

Bruce Silverglade
Director of Legal Affairs

Sandra B. Eskin, Esq.
Of Counsel

Exhibit 1a

Ingredient Labels

INGREDIENTS: ENRICHED FLOUR [WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN B2), FOLIC ACID], VEGETABLE SHORTENING (CONTAINS PARTIALLY HYDROGENATED SOYBEAN AND/OR COTTONSEED OILS), CHEDDAR CHEESE (PASTEURIZED CULTURED MILK, SALT, ENZYMES), CALCIUM CARBONATE, SALT, WHEY, AUTOLYZED YEAST, BUTTERMILK SOLIDS, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE, CORNSTARCH), SUGAR, YEAST, LACTIC ACID, ARTIFICIAL COLORS (ANNATTO, YELLOW 5, YELLOW 6), SODIUM PHOSPHATE, SODIUM CASEINATE, ONION POWDER, ACETIC ACID, XANTHAN GUM, POTASSIUM SORBATE. MAY CONTAIN TRACES OF PEANUTS OR TREE NUTS.

Current

Ingredient Facts

Major Ingredients: Enriched flour (60%) [wheat flour, niacin, reduced iron, thiamine mononitrate (vitamin B1), riboflavin (vitamin B2), folic acid] • Vegetable shortening (20%) (contains partially hydrogenated soybean and/or cottonseed oils) • Cheddar cheese (pasteurized cultured milk, salt, enzymes) • Calcium carbonate • Salt • Whey • Autolyzed yeast • Buttermilk solids • Leavening (sodium acid polyphosphate, sodium bicarbonate, cornstarch) • Sugar • Yeast • Lactic acid.

Contains 2% or less: Artificial colors (annatto, Yellow 5, Yellow 6) • Sodium phosphate • Sodium caseinate • Onion powder • Acetic acid • Xanthan gum • Potassium sorbate.

Allergy Information: May contain traces of peanuts or tree nuts.

Proposed

Exhibit 1b

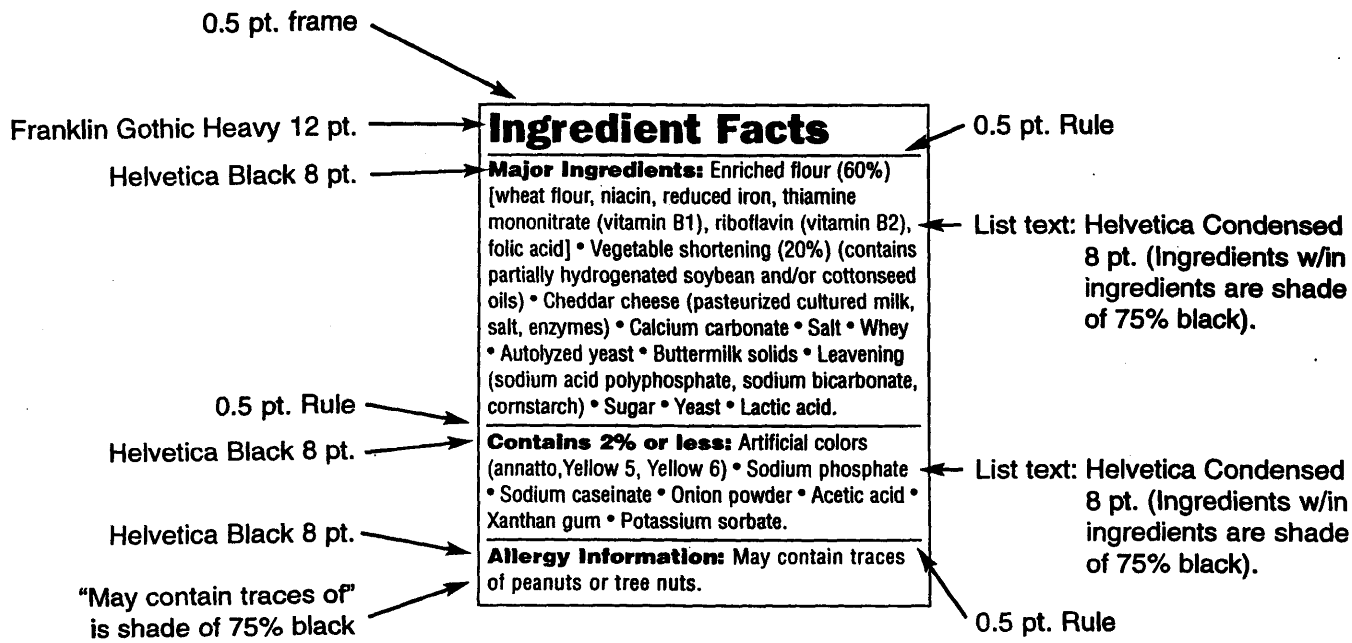

0.5 pt. frame
Franklin Gothic Heavy 12 pt.
Helvetica Black 8 pt.
0.5 pt. Rule
Helvetica Black 8 pt.
Helvetica Black 8 pt.
"May contain traces of" is shade of 75% black
Ingredient Facts
Major Ingredients: Enriched flour (60%) [wheat flour, niacin, reduced iron, thiamine mononitrate (vitamin B1), riboflavin (vitamin B2), folic acid] • Vegetable shortening (20%) (contains partially hydrogenated soybean and/or cottonseed oils) • Cheddar cheese (pasteurized cultured milk, salt, enzymes) • Calcium carbonate • Salt • Whey • Autolyzed yeast • Buttermilk solids • Leavening (sodium acid polyphosphate, sodium bicarbonate, cornstarch) • Sugar • Yeast • Lactic acid.
Contains 2% or less: Artificial colors (annatto,Yellow 5, Yellow 6) • Sodium phosphate • Sodium caseinate • Onion powder • Acetic acid • Xanthan gum • Potassium sorbate.
Allergy Information: May contain traces of peanuts or tree nuts.
0.5 pt. Rule
List text: Helvetica Condensed 8 pt. (Ingredients w/in ingredients are shade of 75% black).
List text: Helvetica Condensed 8 pt. (Ingredients w/in ingredients are shade of 75% black).
0.5 pt. Rule

Exhibit 2

Campbell's®
CONDENSED SOUP
GREAT FOR COOKING
CAMPBELL'S® TASTY 2-STEP MUSHROOM-GARLIC CHICKEN
PREP/COOK TIME: 20 MIN. • SERVES 4
1. BROWN
4 BONELESS CHICKEN BREASTS
2. ADD
SOUP & MILK. COVER & SIMMER UNTIL DONE.
MICROWAVE:
STOVE:
Nutrition Facts
Servings about 2.5
Calories 70
Fat Cal 25
Cream of
MUSHROOM
With ROASTED GARLIC
NET WT. 10 3/4 OZ. (305g)
INGREDIENTS: WATER, MUSHROOMS, MODIFIED FOOD STARCH, CREAM, CONTAINS LESS THAN 2% OF THE FOLLOWING INGREDIENTS: VEGETABLE OIL (CORN, COTTONSEED, PARTIALLY HYDROGENATED SOYBEAN, CANOLA AND OR SOYBEAN), CORNSTARCH, SWEET CREAM BUTTERMILK POWDER, SALT, WHEAT FLOUR, TOMATO PASTE, MONOSODIUM GLUTAMATE, GARLIC FLAVOR (MALTODEXTRIN, GARLIC POWDER, PARTIALLY HYDROGENATED SOYBEAN OIL, DEXTROSE, NATURAL FLAVOR), SOY PROTEIN CONCENTRATE, ONION CONCENTRATE (CONTAINS SUNFLOWER OIL), DEHYDRATED ROASTED GARLIC, POTASSIUM CHLORIDE, MALTODEXTRIN, DISODIUM INOSINATE, DISODIUM GUANYLATE, DEHYDRATED PARSLEY, SPICE EXTRACT, YEAST EXTRACT, WHEY, CARAMEL COLOR, FLAVORING, ENZYME MODIFIED CREAM, CORN SYRUP SOLIDS, BUTTER, MILK FAT, ENZYME MODIFIED BUTTER OIL, ENZYME MODIFIED GOAT MILK (GOAT MILK, SALT, ENZYMES, ACETIC ACID), CREAM POWDER, ENZYME MODIFIED BUTTER, NONFAT DRY MILK, LIPOLYZED BUTTER OIL, OLEIC ACID, BUTTER OIL, LACTIC ACID, BUTTER FLAVOR (ENZYME MODIFIED BUTTER, ACETIC ACID).
CAMPBELL SOUP COMPANY, CAMDEN, NJ, U.S.A. 08103-1701

Exhibit 3

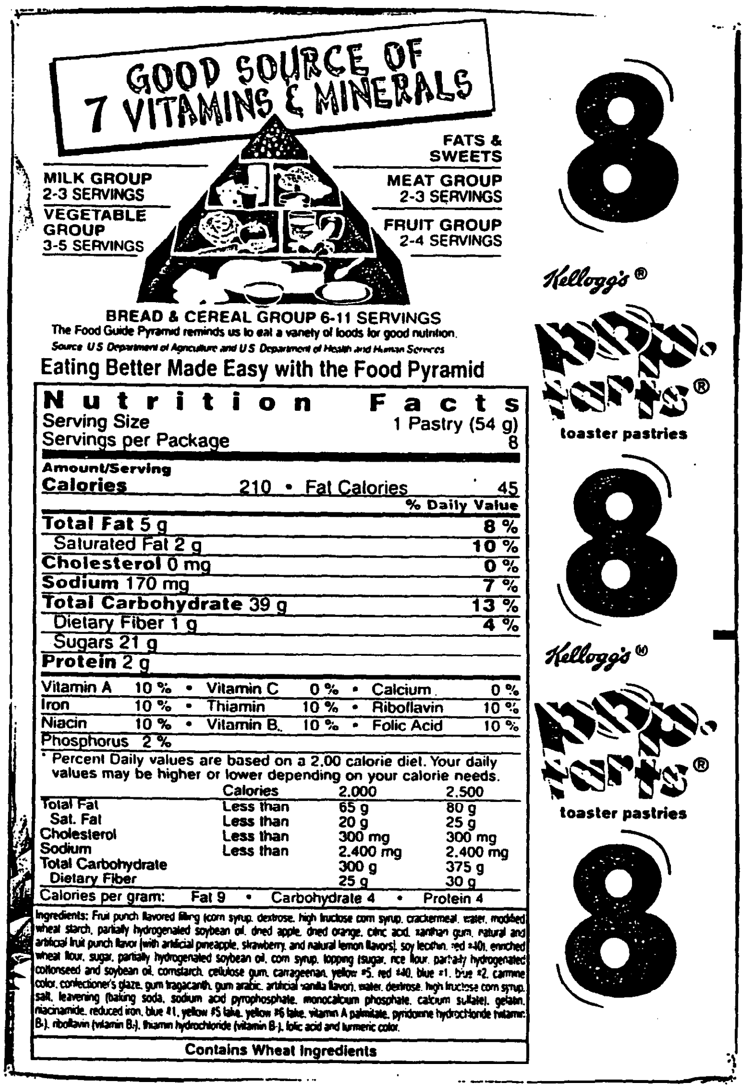

GOOD SOURCE OF
7 VITAMINS & MINERALS
FATS & SWEETS
MILK GROUP
2-3 SERVINGS
MEAT GROUP
2-3 SERVINGS
VEGETABLE GROUP
3-5 SERVINGS
FRUIT GROUP
2-4 SERVINGS
BREAD & CEREAL GROUP 6-11 SERVINGS
The Food Guide Pyramid reminds us to eat a variety of foods for good nutrition.
Source U.S. Department of Agriculture and U.S. Department of Health and Human Services
Eating Better Made Easy with the Food Pyramid
Nutrition Facts
Serving Size 1 Pastry (54 g)
Servings per Package 8
Amount/Serving
Calories 210 • Fat Calories 45
% Daily Value
Total Fat 5 g 8 %
Saturated Fat 2 g 10 %
Cholesterol 0 mg 0 %
Sodium 170 mg 7 %
Total Carbohydrate 39 g 13 %
Dietary Fiber 1 g 4 %
Sugars 21 g
Protein 2 g
Vitamin A 10 % • Vitamin C 0 % • Calcium 0 %
Iron 10 % • Thiamin 10 % • Riboflavin 10 %
Niacin 10 % • Vitamin B[illegible] 10 % • Folic Acid 10 %
Phosphorus 2 %
* Percent Daily values are based on a 2,00 calorie diet. Your daily values may be higher or lower depending on your calorie needs.
Calories 2.000 2.500
Total Fat Less than 65 g 80 g
Sat. Fat Less than 20 g 25 g
Cholesterol Less than 300 mg 300 mg
Sodium Less than 2.400 mg 2.400 mg
Total Carbohydrate 300 g 375 g
Dietary Fiber 25 g 30 g
Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4
Ingredients: Fruit punch flavored filling (corn syrup, dextrose, high fructose corn syrup, crackermeal, water, modified wheat starch, partially hydrogenated soybean oil, dried apple, dried orange, citric acid, xanthan gum, natural and artificial fruit punch flavor [with artificial pineapple, strawberry, and natural lemon flavors], soy lecithin, red #40), enriched wheat flour, sugar, partially hydrogenated soybean oil, corn syrup, topping (sugar, rice flour, partially hydrogenated cottonseed and soybean oil, cornstarch, cellulose gum, carrageenan, yellow #5, red #40, blue #1, blue #2, carmine color, confectioner's glaze, gum tragacanth, gum arabic, artificial vanilla flavor), water, dextrose, high fructose corn syrup, salt, leavening (baking soda, sodium acid pyrophosphate, monocalcium phosphate, calcium sulfate), gelatin, niacinamide, reduced iron, blue #1, yellow #5 lake, yellow #6 lake, vitamin A palmitate, pyridoxine hydrochloride (vitamin B[illegible]), riboflavin (vitamin B[illegible]), thiamin hydrochloride (vitamin B[illegible]), folic acid and turmeric color.
Contains Wheat Ingredients
8
Kellogg's®
toaster pastries
8
Kellogg's®
toaster pastries
8

Exhibit 4

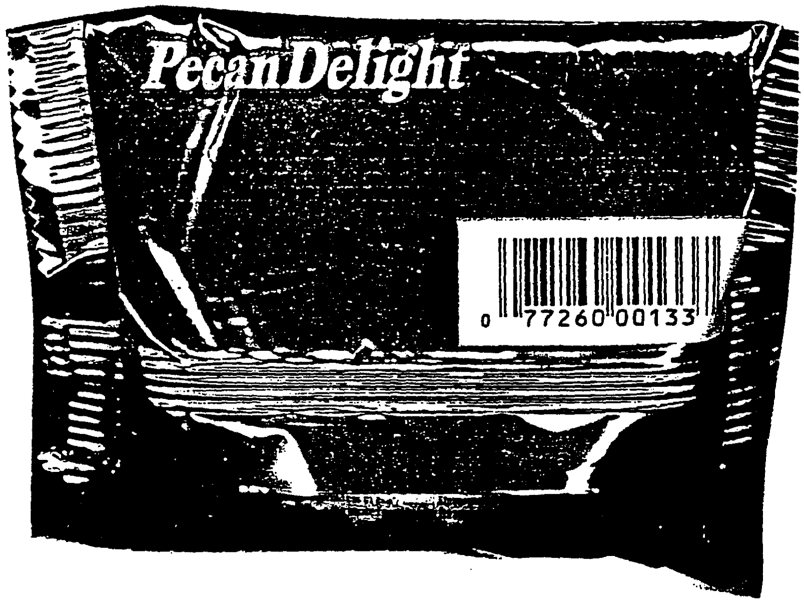


Exhibit 5a

ball park
Fat Free
Franks
Big Delicious Taste
KEEP REFRIGERATED
Amount/serving
Total Fat 0g 0%
Sat. Fat 0g 0%
Sodium 490mg 20%
Total Carb. 6g 2%
Fiber 0g 0%
Sugars 2g
Protein 6g
U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE
NET WT. 14 OZ. (397g)

Exhibit 5b

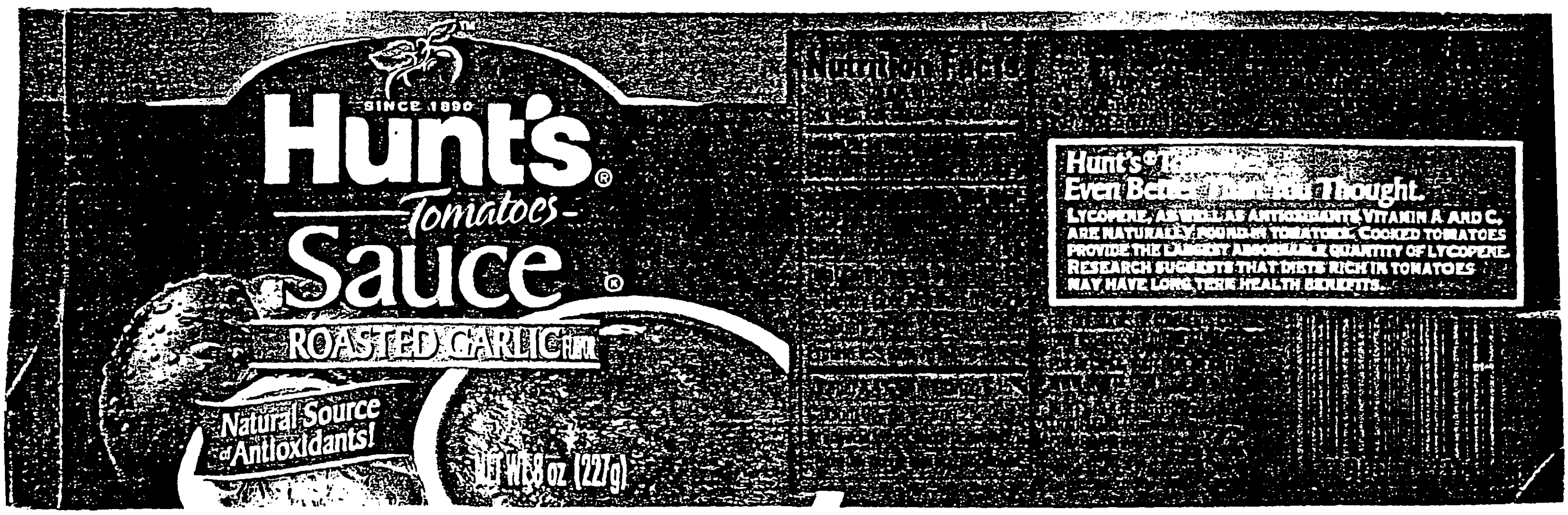

SINCE 1890
Hunt's®
Tomatoes
Sauce®
ROASTED GARLIC
Natural Source of Antioxidants!
NET WT 8 OZ. (227g)
LYCOPENE, AS WELL AS ANTIOXIDANTS VITAMIN A AND C, ARE NATURALLY FOUND IN TOMATOES. COOKED TOMATOES PROVIDE THE LARGEST ABSORBABLE QUANTITY OF LYCOPENE. RESEARCH SUGGESTS THAT DIETS RICH IN TOMATOES MAY HAVE LONG TERM HEALTH BENEFITS.

Exhibit 5c

Nutrition Facts

Serving Size 1/3 cup Mix (44g)
(3 4-inch pancakes)
Servings Per Container about 24

Amount Per Serving

Calories 150 Calories from Fat 20

	% Daily Value**
Total Fat 2g*	**3%**
Saturated Fat 0.5g	**3%**
Cholesterol 0mg	**0%**
Sodium 600mg	**25%**
Total Carbohydrate 30g	**10%**
Dietary Fiber less than 1g	**4%**
Sugars 5g	
Protein 4g	
Vitamin A	0%
Vitamin C	0%
Calcium	10%
Iron	6%
Thiamin	10%
Riboflavin	6%
Niacin	6%
Folic Acid	8%

*Amount in mix. Addition of water does not change nutrient content.

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

INGREDIENTS: BLEACHED ENRICHED FLOUR (BLEACHED FLOUR, MALTED BARLEY FLOUR, NIACIN, IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), YELLOW CORN FLOUR, SUGAR, DEXTROSE, BAKING POWDER (BAKING SODA, MONOCALCIUM PHOSPHATE, SODIUM ALUMINUM PHOSPHATE), PARTIALLY HYDROGENATED VEGETABLE OIL (SOYBEAN, COTTONSEED), SALT, NONFAT MILK, SOY LECITHIN, EGGS, POLYSORBATE 60, CORN SYRUP SOLIDS, MONO- AND DIGLYCERIDES.

MANUFACTURED BY:
THE PILLSBURY COMPANY
2866 PILLSBURY CENTER
MINNEAPOLIS, MN 55402-1464 USA

35% Recycled Fiber

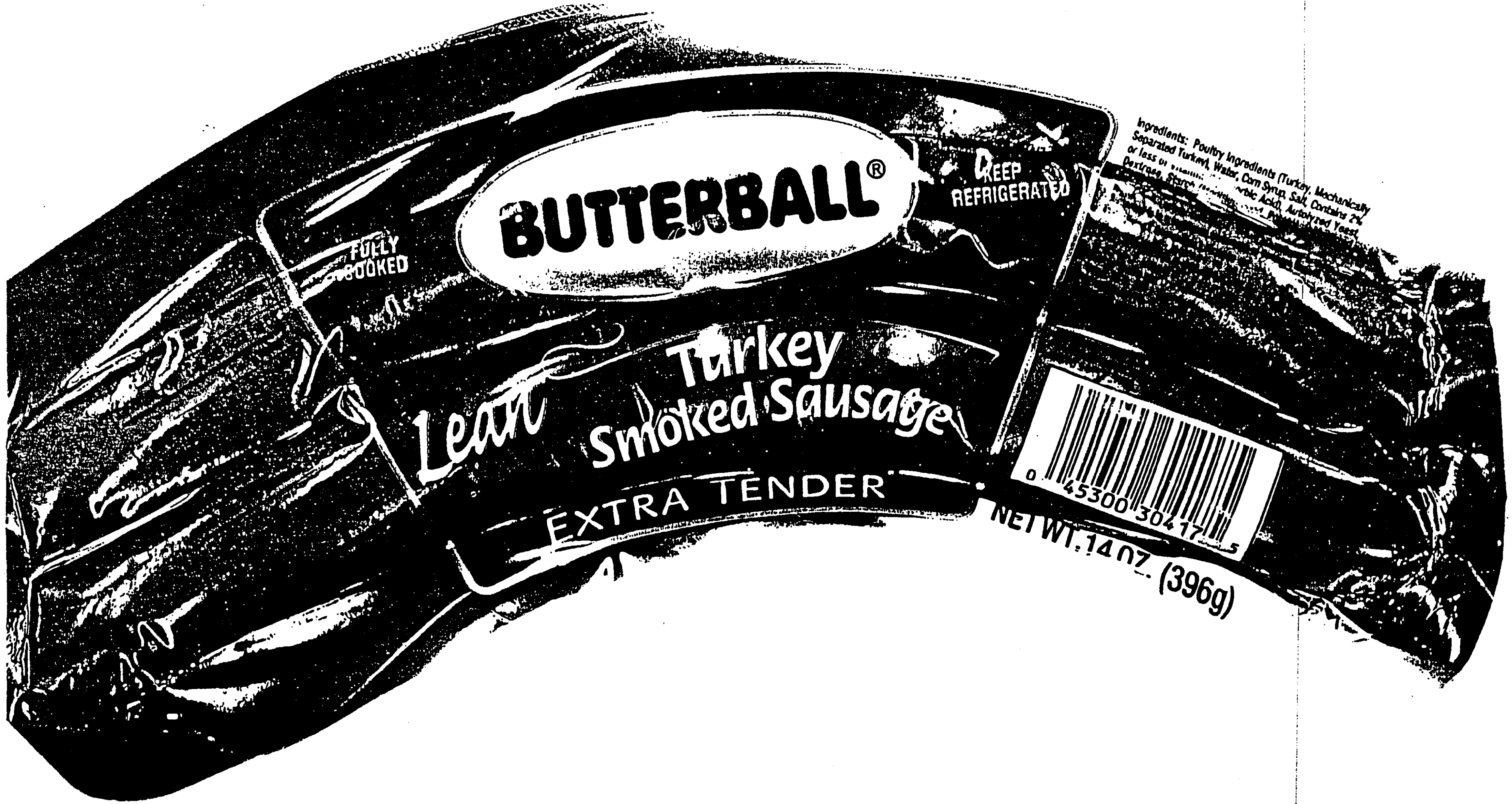

BUTTERBALL®
FULLY COOKED
KEEP REFRIGERATED
Ingredients: Poultry Ingredients (Turkey, Mechanically Separated Turkey), Water, Corn Syrup, Salt, Contains 2%
Lean
Turkey
Smoked Sausage
EXTRA TENDER
NET WT. 14 OZ. (396g)

Exhibit 6

Exhibit 7

Nutrition Facts

Serving Size ½ cup (125g)
Servings Per Container about 2

Amount Per Serving	
Calories 60	Calories from Fat 0
	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**0%**
Cholesterol 0mg	**0%**
Sodium 10mg	**0%**
Total Carbohydrate 11g	**4%**
Dietary Fiber 4g	**16%**
Sugars 6g	
Protein 3g	
Vitamin A 6%	Vitamin C 15%
Calcium 2%	Iron 8%

*Percent Daily Values are based on a 2,000 calorie diet.

NOT A SODIUM-FREE FOOD
INGREDIENTS: PEAS, WATER, SUGAR.

DISTRIBUTED BY DEL MONTE FOODS
SAN FRANCISCO, CA 94105 PACKED IN U.S.A.
WHEN WRITING TO US, PLEASE COPY THE STAMPED CODE FROM THE END OF THE CAN–OR REFER TO THE CODE WHEN CALLING 1-800-543-3090, MON.-FRI. 8 A.M.-5 P.M., PACIFIC TIME.

DEL MONTE® Sweet Peas with No Salt Added are picked fresh at the peak of flavor, then packed fresh to lock in their plump, sweet taste and nutrients. With no artificial additives or preservatives, you get unsurpassed *FreshCut*® flavor, with no salt added–Guaranteed!

0 24142 0 3

PLEASE RECYCLE

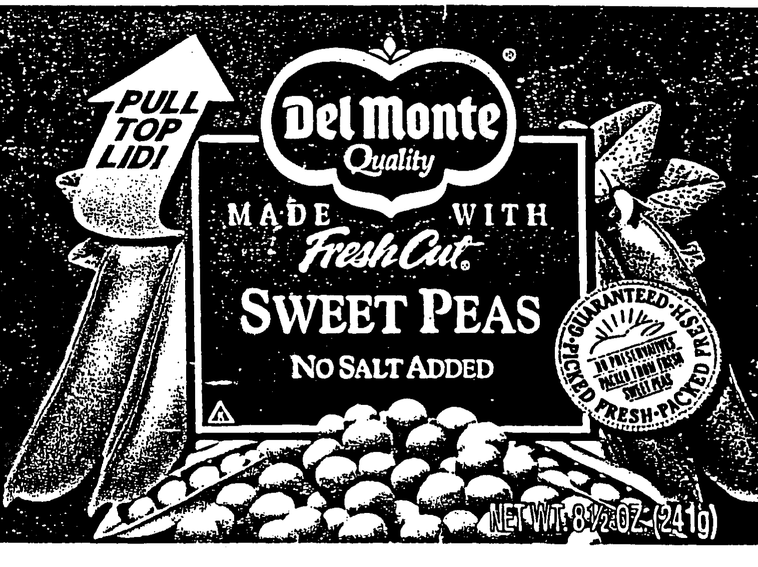
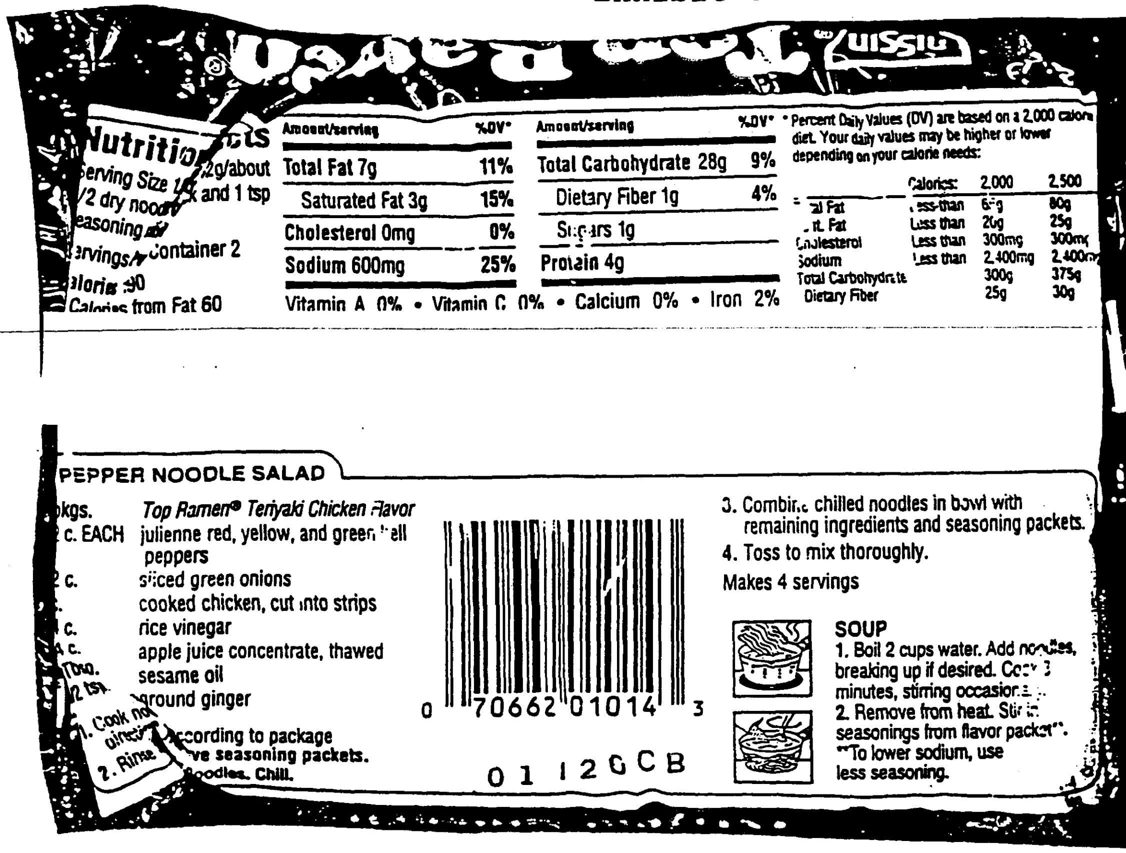
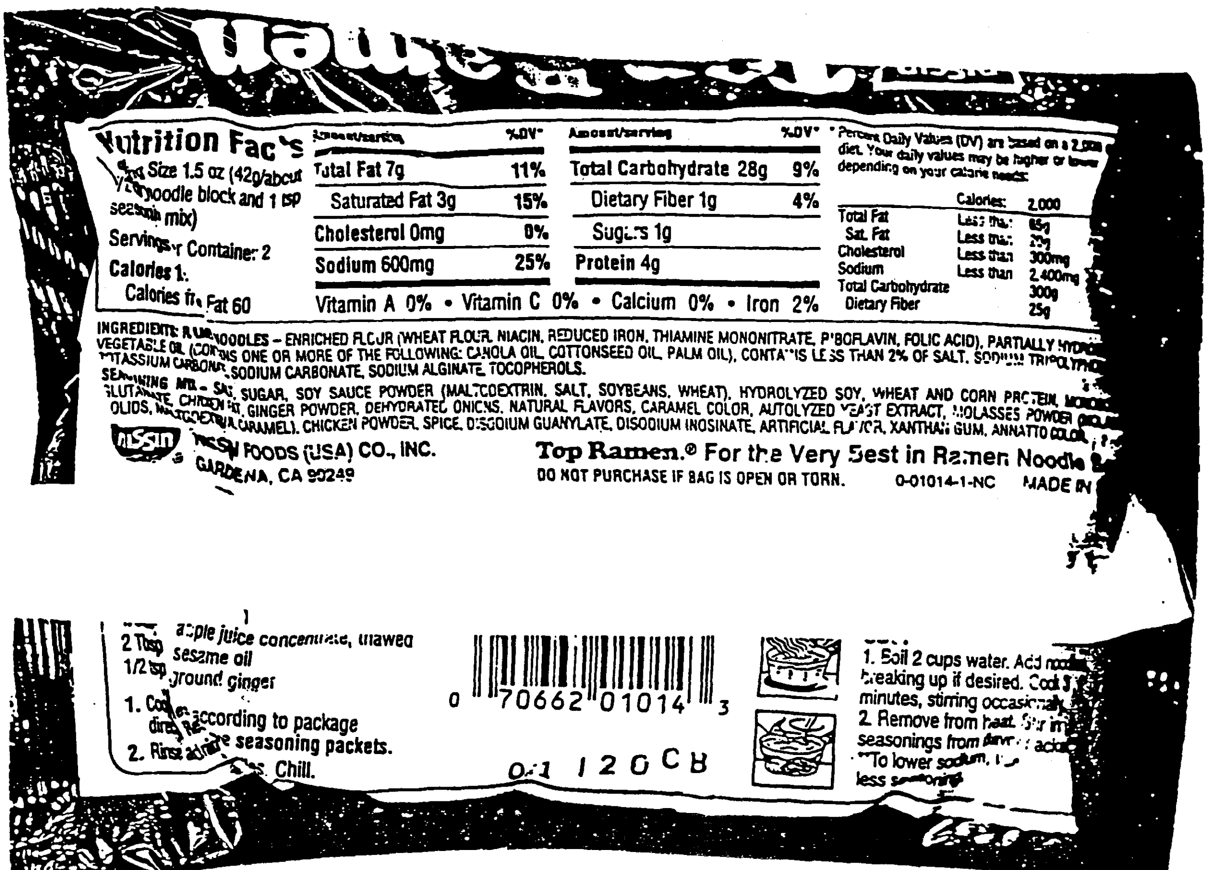


Exhibit 8



-As Packaged



-Flap Folded Back

Exhibit 9

ACTION PLAN FOR THE PROVISION OF USEFUL PRESCRIPTION MEDICINE INFORMATION

Presented to
The Honorable Donna E. Shalala,
Secretary of the Department of Health and Human Services

by the
Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information

DECEMBER 1996

THE KEYSTONE CENTER

P.O. Box 8606, Keystone, Colorado 80435-7998   Phone 303/468-5822   Fax 303/262-0152

The following guidelines reflect widely recognized standards used by designers and publishers of written information to ensure that the materials are legible and readable.[34] Legibility and readability cannot be reduced to a precise formula; rather, they depend on a combination of factors. The pages that follow are examples of information materials that adhere to these guidelines.

- **Prescription medicine information should be printed in no smaller than 10-point type.** Type size is very important to readability. Newspapers are usually printed in 8-point type, while 12 point is generally recommended as the smallest type size to use for materials intended specifically for older persons, who are significant consumers of prescription drugs.

- **Ornate typefaces and italics, which are hard to read, should not be used.** Too much curve or detail obscures the letters and slows reading. A bolder type should be chosen over a thin version of the same style. Opinions vary on whether a "serif" font (as is used in this document) or a "sans serif" font (like this one) is more readable. Many experts recommend that sans serif should be used for headings, while serif style should be used for text.

- **Upper and lower case lettering should be used.** Upper and lower case letters have more variation in shape and are easier to identify than all upper case lettering.

- **Use bold-face type or a box to call attention to important information.** Highlighting or underlining for this purpose can impede readability.

- **Adequate space between letters, lines, and paragraphs enhances readability.** If the lines of text are too close together, the material will be difficult to read. Generally, text should have no more than -3 "kerning" (i.e. space between letters). With 10-point type, 12-point "leading" (i.e., space between lines) is generally recommended. Adequate space between paragraphs and space above and below headings can also facilitate reading.

- **Line length should not be too long.** Optimal line length is approximately 40 letters long (in 10-point or 12-point type).

- **There should be good contrast between the ink and paper colors.** Good contrast will facilitate reading. Black, dark blue, or brown ink on pale yellow or white paper provides the best contrast. Combinations that provide insufficient contrast should be avoided (e.g., brown on gold, blue on green, red on pink). Also, material should be printed on uncoated paper.

- **Short paragraphs and bullets should be used where possible.** This increases the readability of prescription medicine information.

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[34] M.R. Boyce, *Guidelines for Printed Materials for Older Adults* (Lansing, MI: Michigan Health Council, 1981); Association for the Advancement of Retired Persons (AARP), *Truth About Aging: Guidelines for Accurate Communications* (Washington, DC: AARP, 1986); C. Baker, *Just Say It!: How to Write for Readers Who Don't Read Well* (Washington, DC: Plan Incorporated, 1992).